Remarks

Upon entry of the foregoing amendment, claims 112, 115-123, 125, 126, 129-131, 134-149 are pending in this application. Claims 1-111, 113, 114, 127 and 128 have been previously cancelled without prejudice or disclaimer. Claims 124, 132 and 133 are newly cancelled herein. Applicants reserve the right to pursue the subject matter of the cancelled claims (1-111, 113, 114, 124, 127, 128, 132 and 133) in a continuing or divisional application without prejudice or disclaimer. Claims 112, 118, 120, 121, 123 and 125 are newly amended. Claims 135-149 are newly added. Claims 112 and 135 are the independent claims.

Support for the amendment to claim 112 ("hydrated") are found, for example, on page 3, lines 24-25; page 8, lines 26-28; and, elsewhere throughout the specification. Furthermore, the phrase "hydrated skin" finds support, for example, on page 8, lines 21-23, and, elsewhere throughout the specification.

Claim 118 has been amended to correct a grammatical error.

Claim 120 has been amended to more clearly claim the invention.

Claim 121 has been amended to more correctly claim antecedent basis.

Support for the amendments to claim 123 ("from cholera toxin (CT)") are found, for example, in original claim 23, and, elsewhere throughout the specification. Claim 123 has also been amended to more clearly claim the invention.

Claim 125 has been amended to more clearly claim the invention.

Support for new claim 135 is found, for example, on page 1, line 35 through page 2, line 6; page

8, lines 10-38; page 9, lines 1-13; and, elsewhere throughout the specification.

Support for new claim 136 is found, for example, on page 21, lines 23-27; page 23, lines 3-16, and, elsewhere throughout the specification.

Support for new claim 137 is found, for example, on page 8, lines 19-21, and, elsewhere throughout the specification.

Support for new claim 138 is found, for example, in original claim 12, and, elsewhere throughout the specification.

Support for new claim 139 is found, for example, in original claim 14, and, elsewhere throughout the specification.

Support for new claim 140 is found, for example, on page 6, lines 10-11; page 8, lines 5-9, and, elsewhere throughout the specification.

Support for new claim 141 is found, for example, on page 14, line 23, and, elsewhere throughout the specification.

Support for new claim 142 is found, for example, on page 14, line 38, and, elsewhere throughout the specification.

Support for new claim 143 is found, for example, on page 18, lines 30-35, and, elsewhere throughout the specification.

Support for new claim 144 is found, for example, on page 18, lines 7-25; and, elsewhere throughout the specification.

Support for new claim 145 is found, for example, on page 16, lines 3-11; page 17, lines 1-10; and, elsewhere throughout the specification.

Support for new claim 146 is found, for example, on page 16, lines 23-24 and 34-35, and, elsewhere throughout the specification.

Support for new claim 147 is found, for example, on page 18, lines 1-6, 12-15; page 16, lines 3-22; and, elsewhere throughout the specification.

Support for new claim 148 is found, for example, on page 15, line 25, and, elsewhere throughout the specification.

Support for new claim 149 is found, for example, as follows, and, elsewhere throughout the specification:

"application of a hydrating agent" (page 5, lines 25-26);

"application of a patch" (page 23, line 5);

"application of a dressing" (page 23, lines 3-16);

"application of a formulation wherein said formulation is a cream, emulsion, gel, lotion, ointment, paste, solution or suspension" (page 8, lines 19-21); and,

"combinations of any of (a) –(d) above" (page 23, line 3-16).

No new matter is believed to have been added by this amendment. In view of the amendments and following remarks, reconsideration of the rejections and withdrawal thereof is respectfully requested. The Office Action dated September 27, 2004 has been carefully reviewed and the foregoing amendments are made in response thereto.

Rejection of claims under 35 U.S.C. § 112, first paragraph

A. The Office rejected claim 123 under 35 U.S.C. § 112, first paragraph, in that the disclosure allegedly does not reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The Office asserts the specification and claims as originally filed do not provide support for the invention as claimed in claim 123. The rejection is respectfully traversed. Furthermore, the rejection is considered moot in view of newly amended claim 123, as explained below.

In particular, the Office asserts the phrase "formulation comprises an ADP-ribosylating exotoxin B subunit" does not have support in the specification. The Office alleges that support is only found (claim 123) for the B subunit of cholera toxin. Without acquiescing to the propriety of the rejection, Applicants have amended claim 123 to now claim a B subunit from cholera toxin (CT). In view of the amendment to the claim, the rejection is moot. Reconsideration and withdrawal is respectfully requested.

B. The Office rejected claims 112, 115-126 and 129-134 under 35 U.S.C. § 112, first paragraph, because the specification allegedly is not enabling for a method wherein "no hydration of the skin has been performed and wherein a dry formulation is employed." The rejection is respectfully traversed. Without acquiescing to the propriety of the rejection, Applicants have amended claim 112, as discussed below.

In view of the amendment to independent claim 112 and newly presented claim 135, now claiming *inter alia,* "hydrated skin" or a "formulation which is hydrated" the rejection is moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under the Judicially Created Doctrine of Obviousness Type Double Patenting

The Office provisionally rejected claims 112, 115-126 and 129-134 under the judicially created doctrine of obviousness type double patenting as allegedly being:

1) unpatentable over claim 32 of copending application no. 10/633,626 ['626];

2) unpatentable over claims 32 and 33 of copending application no. 10/701,069 ['069]; and,

3) unpatentable over claims 71, 72, 75-87 and 90-97 of copending application no. 09/337,746 ['746].

The obviousness-type double patenting rejection over the '626 application is moot in view of the cancellation of claim 32 from the '626 application. A copy of the third preliminary amendment in the '626 application, canceling claim 32, filed concurrently, is submitted herewith. In view of the cancellation of claim 32, the obviousness-type double patenting rejection should not be maintained over the pending claims.

The obviousness type double patenting rejection over the '069 application is believed to be moot since the '069 application is abandoned.

Submitted herewith is a terminal disclaimer disclaiming the '746 application.

In view of the amendments to the claims and terminal disclaimer submitted herewith, the rejections are moot. Reconsideration and withdrawal of the obviousness-type double patenting rejections is respectfully requested.

Other Matters

Applicants note with appreciation the executed PTO 1449 form, filed at the US PTO with an IDS on February 17, 2004, returned with the September 27, 2004 Office Action.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and the timely allowance of the pending claims. A favorable action is awaited. If, in the opinion of the Examiner, an interview

would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the telephone number provided below.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,
Morgan, Lewis & Bockius LLP

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PATENT
Attorney Docket **056707-5009-01 US**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Gregory M. Glenn *et al.***	)	
U.S. Application No. **10/633,626** (Continuation of U.S. Appl. No. 09/545,417)	)	Group Art Unit: **1653**
Filed: **August 5, 2003**	)	Examiner: **Not Assigned**
For: **Dry Formulation for Transcutaneous Immunization**	)	

THIRD PRELIMINARY AMENDMENT

This third preliminary amendment is being filed prior to first action. Please amend the application as follows:

Amendments to the Claims are reflected in the listing of the claims which begins at page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

1(canceled)

2 (currently amended): A method of inducing an immune response comprising applying a formulation to intact dry skin of a subject, wherein the formulation is comprised of at least one antigen and at least one adjuvant wherein the formulation is applied in dry form; and wherein the formulation is applied in an amount and for a length of time effective to induce an immune response specific for the at least one antigen.

3 (original): The method of Claim 2, wherein the formulation is applied with an occlusive dressing.

4 (original): The method of Claim 3, wherein the occlusive dressing covers a surface area of the intact skin which is larger than at least one draining lymph node field.

5 (original): The method of Claim 2, wherein the formulation consists essentially of antigen and adjuvant.

6 (original): The method of Claim 2, wherein at least one adjuvant is an ADP-ribosylating exotoxin.

7 (previously presented): The method of Claim 2, wherein at least one adjuvant is selected from the group consisting of bacterial DNA, chemokines, tumor necrosis factor alpha, genetically altered toxins, chemically conjugated bacterial ADP ribosylating exotoxins, unmethylated CpG dinucleotides, lipopolysaccharides, and cytokines.

COPY

8-10 (canceled)

11 (original): The method of Claim 2, wherein at least one antigen is derived from a pathogen selected from the group consisting of bacterium, virus, fungus, and parasite.

12 (canceled)

13 (original): The method of Claim 2, wherein at least one antigen is selected from the group consisting of carbohydrate, glycolipid, glycoprotein, lipid, lipoprotein, phospholipid, and polypeptide.

14 (original): The method of Claim 2, wherein the formulation is comprised of an attenuated live virus and at least one antigen is expressed by the attenuated live virus.

15 (canceled)

16 (original): The method of Claim 2, wherein at least one antigen is multivalent.

17-18 (canceled)

19 (original): The method of Claim 2, wherein a single molecule is both an adjuvant and an antigen of the formulation.

20-30 (canceled)

31 (original): The method of Claim 2 further comprising applying alcohol to the intact skin prior to application of the formulation.

32-37 (canceled)

38 (currently amended): A method of ~~immunization~~ inducing an immune response comprising applying a dry formulation to dry skin of a subject, wherein the dry formulation comprises antigen and adjuvant as active ingredients, in an amount and for a time sufficient to induce a systemic or regional immune response, or both, specific for the antigen.

39-45 (canceled)

46 (previously presented): The method of claim 11, wherein said bacterium is anthrax.

47 (previously presented): The method of claim 11, wherein said virus is rabies virus.

48 (previously presented): The method of claim 2, wherein the antigen is an influenza antigen.

49 (previously presented): The method of claim 2, wherein the antigen is an influenza antigen and the adjuvant is an ADP-ribosylating exotoxin.

50 (previously presented): The method of claim 19, wherein the single molecule is heat-labile enterotoxin (LT).

51 (previously presented): The method of claim 3, wherein the formulation is applied with an occlusive dressing.

52 (previously presented): The method of claim 38, wherein the formulation is applied with an occlusive dressing.

53 (previously presented): The method of claim 52, wherein the occlusive dressing further comprises the formulation on an adhesive surface.

54 (previously presented): The method of claim 38, wherein the antigen is an influenza antigen.

55 (previously presented): The method of claim 38, wherein the antigen is an influenza antigen and the adjuvant is an ADP-ribosylating exotoxin.

56 (previously presented): The method of claim 38, wherein a single molecule is both an adjuvant and an antigen of the formulation.

57 (previously presented): The method of claim 56, wherein the single molecule is heat-labile enterotoxin (LT).

58 (previously presented): The method of claim 38, wherein at least one antigen is derived from a pathogen selected from the group consisting of bacterium, virus, fungus, and parasite.

59 (previously presented): The method of claim 58, wherein the bacterium is anthrax.

60 (previously presented): The method of claim 58, wherein the virus is rabies virus.

REMARKS

Upon entry of the foregoing amendment, claims 2-7, 11, 13, 14, 16, 19, 31, 38 and 46-60 are pending in this application. Claim 32 is newly canceled herein without prejudice or disclaimer. Claims 2 and 38 are newly amended herein. Claims 1, 8-10, 12, 15, 17, 18, 20-30, 33-37 and 39-45 have been canceled without prejudice or disclaimer. Applicants reserve the right to pursue claims directed to the canceled subject matter in a continuing or divisional application. Claims 2-7, 11, 13, 14, 16, 19, 31, 38 and 46-60 are currently under examination.

Support for the amendments to claims 2 and 38, now claiming application of a dry formulation to dry skin, is found, for example, page 40, lines 13-21, and, elsewhere throughout the specification. The amendment to claim 38, changing "immunization" to "inducing an immune response," was done to correct antecedent basis.

No new matter is believed to have been added. In view of the amendments and following remarks, reconsideration of the rejections and withdrawal thereof is respectfully requested.

Conclusion

The foregoing amendments and remarks are being made to place the application in condition for allowance. Applicants respectfully request reconsideration and timely allowance of the pending claims. A favorable action is awaited. Should the Examiner believe an interview would be helpful to further allowance of this application, the Examiner is invited to telephone the undersigned at his convenience.

Except for issue fees payable under 37 C.F.R. § 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, including any required

extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **Constructive Petition for Extension of Time** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully submitted,
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